

REMARKS

The claims have been amended to clarify that the factor VIII which is being stabilized by freeze-drying in the presence of trehalose is “native” Factor VIII, that is, a Factor VIII that is not in the form that has been activated by thrombin and thus not the heterotrimer “activated” Factor VIII described by Curtis. As is clear from a reading of Curtis itself, unless Factor VIII (prepared either recombinantly or isolated from plasma) is treated with an activating agent, such as thrombin, it does not assume its activated form. Only by treatment with these activating agents is the heterotrimer obtained. As the herein application contains no such steps, and as, without further definition, the term “Factor VIII” would be understood to refer to the unactivated form, it is clear that the proposed amendment is fully supported by the specification. This is also attested by Dr. Preston’s declaration of record.

This is especially clear from the discussion in the Curtis document cited by the Office which emphasizes that activated Factor VIII is something entirely different from Factor VIII that has not been treated with thrombin. The Curtis document itself consistently uses “Factor VIII” to describe Factor VIII which has not been activated and “activated Factor VIII” to refer to the treated form.

It is settled that features inherent in a description need not be recited *in haec verba* in order to support wording of the claim. See, for example, *Kennecott Corp. v. Kyocera Int’l, Inc.*, 835 F2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987) where the term “equiaxial” in the claims was found to be supported by a priority document disclosing a method which would necessarily result in an equiaxial crystal even though that word was not used in the specification. A copy of this case is attached for the convenience of the Examiner.

It is believed that the Office recognizes the validity of the foregoing argument, as the term “native Factor VIII” was not objected to, and the meaning of this term as distinguishing

activated Factor VIII was recognized, for example, in an Office action issued in the parent application, Serial No. 08/875,796 mailed 9 September 2002. As stated on page 7 of that document:

It is noted, as discussed in the Rule 132 declaration of Dr. Preston that "native" and "activated" Factor VIII are widely recognized as being different entities, native Factor VIII being proteolytically cleaved to result in active Factor VIII.

The objection at that point was one of lack of clarity:

However, only claims 24 and 27 explicitly recite "native" Factor VIII. The remaining claims either do not limit the Factor VIII or recite recombinant Factor VIII. Thus the unqualified term "Factor VIII" in claims 7 and 26 encompasses the activated Factor VIII...

The claims as now amended clearly are limited to "native" Factor VIII since claim 14 recites this limitation and claims 15 and 16 are dependent thereon. Further, it is noted with appreciation that claim 15, which recited "native Factor VIII" was not included in the rejection for anticipation over Curtis.

No new matter has been added and entry of the amendment is respectfully requested.

The claims have also been amended to emphasize that it is an aliquot of the aqueous solution (not a nebulized droplet) that is freeze dried. Support for this language is found in Examples 1 and 2.

The Art Rejections

Claims 14 and 16 were rejected under 35 U.S.C. § 102(e) as anticipated by Curtis, *et al.* (U.S. patent 5,824,780). It will immediately be apparent that the claims as amended are not anticipated by this document, as the limitation to native Factor VIII of claim 15, which was not included in this rejection, is now a limitation of all of claims 14-16.

The exclusion of claim 15 was proper since the sections quoted by the Office in support of the rejection are clear that it is the activated heterotrimer which is the subject of the processes described in Curtis.

The discussion cited by the Office at column 5, lines 30-43, lists the possible addition of stabilizers to Factor VIII and to its activated form. However, when lyophilization is discussed in that paragraph, it refers only to activated Factor VIII, not to the untreated Factor VIII starting material. The storing at reduced temperatures referred to in the Office action as described at column 5, lines 4-6, does not appear at that location; perhaps lines 39-41 are intended. In any case, these lines refer to the heterotrimer.

A review of the examples demonstrates that the Factor VIII of the present claims, when used as a starting material, is neither mixed with trehalose nor lyophilized. In Example 1, for example, the dialyzed Factor VIII preparation (dialysis would not remove any albumin) is simply stored at -20°C. No mention of lyophilization. Similarly, in Example 2, the dialyzed material is simply frozen, apparently remaining in solution.

In summary, the '780 patent provides zero guidance to the reader for preserving native Factor VIII in its natural form not converted to the heterotrimer by thrombin treatment; any conclusion regarding stabilizing by freeze-drying or lyophilizing in the presence of trehalose and the absence of albumin, even when cobbled together from disparate portions of the specification, applies only to activated, heterotrimeric Factor VIII.

Claims 14-16 were rejected as assertedly obvious over Curtis '780 in view of Livesey, *et al.* (U.S. patent 5,364,756).

As a preliminary matter, the Office recognizes the possibility that the '780 patent does not anticipate claims 14 and 16 (presumably because freeze-drying in the presence of any form

of Factor VIII in the presence of trehalose and the absence of albumin is not a necessary outcome as required for anticipation to be found (*Schering Corp. v. Geneva Pharmaceuticals*, 339 F3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991); and *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 64 USPQ2d 1292 (Fed. Cir. 2002)). However, the Office asserts “one reading only the ‘780 patent clearly would have been motivated to have lyophilized an albumin-free preparation of Factor VIII and trehalose.”

As set forth above, regardless of whether this suggestion is even made with respect to the activated Factor VIII heterotrimer, clearly the ‘780 patent does not suggest or motivate the reader to carry out such a process with the Factor VIII in its untreated form, as it is completely silent on this subject. In addition, the ‘780 emphasizes that the activated and nonactivated forms are very different - e.g. at column 1, lines 37-51, and column 6, lines 51-56. For this reason alone, applicant respectfully suggests, this basis for rejection should fail.

But there are other reasons. A fair reading of the secondary document, Livesey, makes it transparent that it is not an aqueous solution of Factor VIII, as required by all of claims 14-16, that is subjected to the process of Livesey, but rather a suspension of essentially insoluble biological materials.

We can start with the title “Method of Cryopreserving a *Suspension* of Biological Material.” Clearly, aqueous solutions are not “suspensions.” Applicant is sure the Office is aware of this, but for completeness, the Random House Webster’s Unabridged Dictionary of 1998 defines suspension as “the state in which the particles of a substance are mixed with a fluid but are undissolved.” On the other hand, a solution is defined in the same source as “a homogeneous, molecular mixture of two or more substances.” A review of Livesey makes it

clear that indeed “suspensions” are intended. This is consistent throughout the text, starting with the description of the “field” at column 1, lines 18-20. All of the exemplified biological materials are of such a nature that they would not dissolve – *e.g.*, cells and viruses. Factor VIII, on the other hand, is an extremely soluble protein and is not exemplified. Livesey itself elaborates on the definition of “suspension,” for example, in column 3, lines 45-51, which state that the invention relates to a method to preserve “microscopic biological materials which are generally prepared in a suspension. As used in this application, suspensions also include emulsions.” There is no statement that suspensions somehow would also include solutions. Indeed, to do so would result in a definition of suspensions that is completely inconsistent with its ordinary meaning. The patentee is allowed to use such a definition, but if that is to be the case, the patentee must explicitly define the term in this way, and Livesey has not.

Lines 52, *et seq.*, go on to say that a “cryosolution” of the biological material includes “an appropriate buffer, one or more cryoprotectants and/or dry protectants and a *suspension* of the biological material.” Thus, though the word “cryosolution” is used, the biological material itself is in suspension. This is particularly clear when the materials that are intended to be cryopreserved are set forth in column 4, at lines 57-64. All of these materials, with the sole exception of Factor VIII, are clearly microscopic particles that cannot be dissolved.

Of course, a suspension of Factor VIII could also be prepared, but as Factor VIII is a highly soluble protein, it would be necessary to denature it in order to accomplish this result. Clearly that is not the thrust of Livesey. Again, in column 5, in describing the preparation of the “cryosolution,” Livesey refers to a *suspension* of the biological material in buffers or cryoprotectants before microdroplets are obtained by nebulizing. In column 8, lines 10-12, Livesey explicitly states that the “cryosolution” comprises “a biological *suspension* and

appropriate buffer and one or more cryoprotectants and/or dry protectants;” this is reemphasized at lines 25-26 the biological sample is “resuspended” in a compatible solution.

Thus, a first reason that Livesey’s process is not applicable to Factor VIII of either activated or not activated form is that it is directed to suspensions of biological materials and the only suspension of Factor VIII that could possibly be prepared is a denatured form or Factor VIII adsorbed to a solid support. However this might be accomplished, the Factor VIII would not be in aqueous solution as required by the claims. As to the requirement that the freeze drying be performed on an aqueous solution, the Office states that the nebulized droplets of the Livesey process are “aqueous solutions.” They are not; they are suspensions. In addition the claims as amended require freeze drying of an “aliquot” which clearly excludes nebulized microdroplets.

A second reason that Livesey fails to suggest the method of the invention is that the use of trehalose is not pointed to specifically; rather, trehalose appears in a general discussion of a number of possible protectants in column 9, lines 6-11. There is no particular reason for the reader of Livesey to focus on trehalose, and certainly no reason that the reader would deliberately exclude albumin which is itself suggested as a stabilizer. In listing both trehalose and albumin in column 9, the possibilities explicitly include “and combinations thereof” at line 11.

The Office quotes a section related to dry protectants rather than cryoprotectants in asserting that albumin would be left out of the composition simply because it is left off the list. However, that list, quoted at page 9, lines 16-32, refers to “protein stabilizers” in general, in combination with various other stabilizers such as trehalose. Taken as a whole, column 9 certainly would only suggest trehalose in the absence of albumin if the disclosure of the present

invention were read into it. Indeed, column 9, line 38, explicitly suggests the combination of trehalose and human serum albumin.

The Office further refers to example 5 of Livesey, the only example that is not directed specifically to suspensions of cells. That example, however, is not directed to anything analogous to Factor VIII; it is a particulate attenuated poliomyelitis virus which includes not only proteins (as do the cells of the previous examples) but also nucleic acids. In any event, the preservation is of an intact virus which is preserved as a *suspension* not in the form of an aqueous solution (see column 23, lines 38-40). Example 5 has nothing whatsoever to do with Factor VIII or with the treatment of an aqueous solution.

Finally, the Office points to claim 17, which indicates that the biological material “comprises” Factor VIII. First, the open language “comprising” does not direct the reader to a composition which contains only Factor VIII as the only biological material *per se*. And it clearly does not exclude albumin from the composition. Second, claim 17 refers to claim 1, which requires a method for preserving a “suspension” of biological materials. Thus, whatever method might be suggested by claim 17, such method does not include freeze-drying an aqueous solution of a biological material comprising Factor VIII. And it does not suggest freeze-drying anything in the absence of albumin.

Respectfully, applicant points out that the Office has not indicated in what way the combination of Livesey and Curtis, even assuming they are rightfully combined, would suggest the invention as claimed. Possibly this is because they do not. In addition, there is no reason to combine them. Livesey is clearly concerned with the cryopreservation of suspensions of complex biological materials such as cells. It is not focused on Factor VIII which is merely listed, undoubtedly mistakenly, among the biological materials which can readily be suspended

and subjected to the Livesey process. Even if the inclusion of Factor VIII is not an out-and-out mistake, and even if one overlooks the requirement in Livesey that the Factor VIII be suspended (though that is required by the claims), the Curtis document is not concerned with the preservation of anything except activated Factor VIII which is never mentioned in Livesey; Curtis is focused entirely on the preparation and stabilization of a heterotrimeric Factor VIII, completely different from any Factor VIII of Livesey and of the present claims. What motivation is there then to combine these?

The only motivation provided by the Office appears in the "Response to Arguments" on page 8 of the Office action. The stated basis for motivation rests on the erroneous assumption that the disclosure of the '780 patent provides direct motivation for adding trehalose to an aqueous solution of Factor VIII and lyophilizing. At best, the '780 patent provides motivation to add trehalose (among other things) to an aqueous solution of heterotrimeric Factor VIII and lyophilizing the resulting solution. Thus, the fundamental assumption on which "motivation" rests is in error. The disclosure of Livesey far from verifies the specific suggestion of trehalose as a cryoprotectant; trehalose is merely mentioned among many other agents, including proteins. Livesey also does not suggest the absence of albumin in this context. There is no common problem to be solved (Factor VIII and activated Factor VIII are not the same protein), there is no suggestion in either document to look to the other, and neither document is notorious in the field. Thus, the three rationales recognized as suitable to support motivation in *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) are not present.

Accordingly, respectfully, applicant believes that this basis for rejection should be withdrawn.

Finally, all claims were rejected as obvious over the combination of Curtis '780 in view of Livesey '756 and further in view of Bhattacharva (U.S. patent 5,288,853).

Applicant recognizes that Bhattacharva suggests histidine as a favorable buffer for Factor VIII containing preparations. However, this basis for rejection must fail for the same reasons argued above with respect to claims 14-16. In addition, Bhattacharva explicitly teaches the addition of albumin to Factor VIII solutions subject to lyophilization, *e.g.* at column 9, lines 33-43, column 10, lines 51-56 and column 12, lines 33-36. Accordingly, this basis for rejection, too, may be withdrawn.

Finally, as a coda, applicant notes that the Office argues that in Livesey, "the droplets in fact consist of aqueous solutions." This is clearly not the case. It is explicit in Livesey that these droplets contain suspensions of the biological materials and are not aqueous solutions at all. In addition the claims as amended further exclude nebulized microdroplets by requiring that an aliquot be freeze dried.

CONCLUSION

The primary reference cited, Curtis '780, is directed to stabilization of an entirely different protein from that which is the subject of the present claims, namely "native" Factor VIII in its unactivated form. These are entirely different molecules which have entirely different characteristics. The description of Curtis '780 is thus irrelevant to the Factor VIII of the present claims.

The Livesey, *et al.*, document is irrelevant as well because it requires "suspensions" of biological materials. The present claims require freeze-drying of an aqueous solution.

There is no motivation provided to combine Livesey with Curtis, and even when the combination is made (as neither document is relevant to the claimed subject matter), the combination does not suggest the present invention.

Respectfully, applicant requests that claims 14-16 and 20-22 be passed to issue. Should the Examiner believe that some matters could be resolved in a telephonic or personal interview, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 559662000101.

Respectfully submitted,

Dated: June 9, 2004

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factors: (1) the nature of the plaintiff's mark; (2) the similarity of the marks at issue; (3) the similarity of the products the marks represent; (4) the similarity of the parties' retail outlets and customers; (5) the nature of the parties' advertising; (6) the defendant's intent; and (7) the extent of actual confusion. *See Ambrit, Inc. v. Kraft, Inc.*, 812 F.2d 1531, 1538 [1 USPQ2d 1161, 1166-67] (11th Cir. 1986), *cert. denied*, ___ U.S. ___, 107 S.Ct. 1983, 95 L.Ed.2d 822 (1987); *Conagra, Inc. v. Singleton*, 743 F.2d 1508, 1514 [224 USPQ 552, 556] (11th Cir. 1984); *Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.*, 716 F.2d 833, 840 [222 USPQ 10, 16-17] (11th Cir. 1983). The extent to which two marks are confusingly similar cannot be assessed without considering all seven factors to ensure that the determination is made in light of the totality of the circumstances. Here, however, the district court ignored six of the seven factors. In finding that "Surfari" is not confusingly similar to "Sun Fari" the court stated:

[T]he word "Surfari" is not bifurcated as is "Sun Fari" in plaintiffs exhibits 3 and 6. No internal upper case letters are used in ["Surfari"]. The script in ["Surfari"] is noticeably different from that used in ["Sun Fari"]. As it appears in plaintiff's exhibit 19, the "Surfari" mark is not substantially different from the word "safari," with which pith helmets are commonly associated.

The court incorrectly focused solely on the degree of visual similarity between the two marks. "Equally as significant as the general appearance of the trademarks is their use in the public market, their effect upon dealers, purchasers and other competitors, the relationship of the trademark's owners, . . . how they develop their business, and whether they are acting *bona* or *mala fide*." *Sun-Fun Prods., Inc. v. Suntan Research & Dev. Inc.*, 656 F.2d 186, 189 [213 USPQ 91, 94] (5th Cir. Unit B 1981) (quoting 3 R. Callmann, *The Law of Unfair Competition, Trademarks and Monopolies* §82.2 (3d ed. 1969)).

A district court's failure to consider all the factors relevant to the issue of whether two marks are confusingly similar does not necessarily constitute reversible error. Indeed, we may affirm an ultimate finding on the issue of confusion that is not clearly erroneous, even when the district court fails to consider all seven factors. *See, e.g., University of Georgia Athletic Ass'n v. Laite*, 756 F.2d 1535, 1542-43 [225 USPQ 1122, 1127-28] (11th Cir. 1985); *Safeway Stores, Inc. v. Safeway Discount Drugs, Inc.*, 675 F.2d 1160, 1163-64 & n.3 [216 USPQ 599,

601-02 & n.3] (11th Cir. 1982).⁷ Here, however, the district court completely disregarded the proper analysis, and we are left with an insufficient basis for determining whether its finding that "Surfari" is not confusingly similar to "Sun Fari" is clearly erroneous. We therefore vacate that portion of the district court's judgment and remand the case for proceedings consistent with this opinion.

REVERSED in part, VACATED in part and REMANDED with instructions.

Court of Appeals, Federal Circuit

Kennecott Corp. v. Kyocera International Inc.

No. 87-1151

Decided December 22, 1987

PATENTS

1. Practice and procedure in Patent and Trademark Office — Prosecution — Filing date (§110.0906)

Patentability/Validity — In general (§115.01)

Patentability/Validity — Adequacy of disclosure (§115.11)

Grant of summary judgment to patent infringement defendant on grounds that pat-

⁷ There has been some confusion over the effect of a district court's failure to use the proper analysis in determining the likelihood of confusion. Our decisions in *Laite* and *Safeway Stores* suggest that such an error cannot by itself constitute reversible error. *See also Sun Banks of Florida, Inc. v. Sun Fed. Sav. & Loan Ass'n*, 651 F.2d 311, 314 [211 USPQ 844, 846] (5th Cir. 1981). Other decisions, however, suggest that the failure to use the proper analysis is a legal error which is subject to review apart from whether the court's ultimate finding on the confusion issue is clearly erroneous. *See, e.g., Ambrit*, 812 F.2d at 1538-39 [1 USPQ2d at 1166-67]; *Jellibeans*, 716 F.2d at 840 [222 USPQ at 10]; *Fuji Photo Film Co., Inc. v. Shinohara Shoji Kabushiki Kaisha*, 754 F.2d 591, 594-95 & n.4 [225 USPQ 540, 542 & n.4] (5th Cir. 1985).

Whether two marks are confusingly similar is a question of fact, and ordinarily we should limit our inquiry to whether the district court's ultimate finding on the issue is clearly erroneous. In some cases, however, the incompleteness of the district court's findings may preclude such an inquiry, necessitating a remand to the district court for the proper analysis.

ent holder's ceramic product patent was invalid under patentability bar of being "on sale" prior to application date under 35 USC 102(b), is error since earlier application for parent process patent inherently described property of equiaxed microstructured ceramic product by its disclosure, and, despite not specifically naming such ceramic product, complies with 35 USC 120 and 112 for purposes of claiming benefit of earlier prior-to-sale application filing date of parent patent, and thus plaintiff's ceramic product patent is valid.

Particular patents — Chemical — Ceramic body

4,179,299, Coppola, Hailey and McMurtry, sintered alpha silicon carbide ceramic body having equiaxed microstructure, a crystal structure whose submicron grain sizes of silicon carbide are not highly elongated, do not have exaggerated grain growth, and are within a maximum-minimum dimension ratio of less than 3:1, holding of invalidity reversed.

Appeal from the U.S. District Court for the Southern District of California, Rhoades, J.

Plaintiff, Kennecott Corp., brought patent action against Kyocera International Inc. and Kyoto Ceramic Co. Ltd. From grant of summary judgment to defendant holding plaintiff's patent invalid, plaintiff appeals. Reversed.

Clyde F. Willian (Willian Brinks Olds Hofer, Gilson & Lione, Jack C. Berenzweig, and Raymond W. Green, with him on brief), Chicago, Ill., for plaintiff-appellant Kennecott Corp.

Paul L. Gardner (Spensley Horn Jubas & Lubitz, Stuart Lubitz, Saul Epstein, and David L. Henty, with him on brief), Los Angeles, Calif., for defendants-appellees Kyocera International Inc. and Kyoto Ceramic Co. Ltd.

Before Markey, Chief Judge, and Davis and Newman, Circuit Judges.

Newman, Circuit Judge.

Kennecott Corporation appeals the final judgment of the United States District Court for the Southern District of California,¹ in

¹ *Kennecott Corporation v. Kyocera International, Inc. and Kyoto Ceramic Co., Ltd.*, No. 80-0516 R(M) (S.D.Calif. Dec. 7, 1986).

which the district court granted summary judgment to the defendants Kyocera International and Kyoto Ceramic Co., Ltd. (together "Kyocera"), holding that United States Patent No. 4,179,299 ("the '299 patent") is invalid in terms of the "on sale" bar of 35 U.S.C. §102(b). Kennecott's claim of patent infringement was dismissed. We reverse.

The Controlling Question

The judgment of invalidity turned on the sole question of whether the claims of the '299 patent are entitled, as a matter of law, to the benefit of the filing date of its parent patent application which eventually issued as U.S. Patent No. 4,312,954 ("the '954 application"), filed on June 5, 1975. If so entitled, the sales events in 1977 can not effect an invalidity bar. If not so entitled, Kennecott admits that its sales activities occurred more than one year before May 1, 1978, the filing date of the continuation-in-part application that issued as the '299 patent.

Background

On summary judgment all facts material to the result must be either undisputed or, if disputed, must be resolved in favor of the party opposing summary judgment. *Litton Industrial Products, Inc. v. Solid State Systems Corp.*, 755 F.2d 158, 163, 225 USPQ 34, 37 (Fed. Cir. 1985). Rule 56, Fed. R. Civ. Proc. The question of the sufficiency of the disclosure of the '954 application to support the '299 claims is a matter of law based on underlying facts. All facts material to the issue are here deemed undisputed, based on admissions by Kyocera for the purpose of its motion for summary judgment.

Kyocera states in its brief on appeal that it did not concede or admit all the facts that Kennecott says it did. The district court found, however, that:

Finding 11. For the purposes of this Motion only, the material facts set forth in all of the affidavits and in all of the exhibits submitted by plaintiff in opposition to Defendants' Motion, are undisputed by defendants.

Kyocera has not assigned error to this finding, and it is bound thereby.

The continuation-in-part '299 application contains a substantial part of the disclosure of the '954 parent application, plus a description of and photomicrographs showing the

equiaxed microstructure.² It is not disputed that the photomicrographs were of the product made and described in the '954 application, and produced in the original examples.

The '299 patent claims contain the words "equiaxed microstructure" that were not present in the '954 specification and claims. This is the only difference at issue. '299 patent claim 1 is representative:

1. A sintered ceramic body consisting essentially of:

(a) from about 91 to about 99.85% by weight silicon carbide, wherein at least 95% by weight of the silicon carbide is of the alpha phase;

(b) up to about 5.0% by weight carbonized organic material;

(c) from about 0.15 to about 3.0% by weight boron; and

(d) up to about 1.0% by weight additional carbon;

and having a predominantly equiaxed microstructure.

Pertinent undisputed or conceded facts include the following:

the high (over 95%) alpha silicon carbide ceramic body that is described in the '954 application has an equiaxed microstructure;

the '954 application does not mention the equiaxed microstructure of the high-alpha silicon carbide ceramic body, nor state the requirements for forming such microstructure;

the inventors knew that the high-alpha silicon carbide ceramic body had an equiaxed microstructure, and it was known that ceramics from high-alpha silicon carbide could have this structure;

examples 1-30 in the '954 application, all the examples using high-alpha silicon carbide, all produce a ceramic body having an equiaxed microstructure;

the method set forth in the '954 application using the high-alpha silicon carbide

invariably produces a ceramic product having an equiaxed microstructure.

Kennecott asserts that the equiaxed microstructure is inherent in the structure produced in the '954 application; and that the '299 claims, which specifically name the equiaxed structure, therefore enjoy the benefit of the earlier filing date. Kennecott also asserts, and Kyocera denies, that Kyocera conceded the question of inherency in the course of conceding all disputed facts on its motion for summary judgment.

It is apparent that Kyocera conceded the factual premises³ of inherency by conceding that examples 1-30 produced, without undue experimentation, a product having an equiaxed microstructure. What is disputed is the legal implication of this inherent production of an equiaxed product.

The district court concluded that for the '954 specification to meet the written description requirement, one reading the specification must know from the "four corners" of the document, without recourse to information outside the specification, that the ceramic product has an equiaxed microstructure. The district court held that the specification of the '954 application met the enablement requirement of section 112 but not the written description requirement, and thus that it was immaterial that the product disclosed in the '954 application was the same as that claimed in the '299 patent.

Discussion

For the '299 claims to receive the benefit of the '954 application's filing date, 35 U.S.C. § 120 requires, *inter alia*, that the invention of the claims be disclosed in the '954 specification in the manner required by 35 U.S.C. § 112, first paragraph, which provides:

§ 112 ¶1: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

² "Equiaxed microstructure" is the crystal structure of the silicon carbide in submicron size grains that are not highly elongated and that do not have exaggerated grain growth. As defined in the '299 patent the ratio of the maximum dimension of the grains to the minimum dimension is less than 3:1.

³ Kyocera raises on this appeal factual issues that appear to contradict its concessions before the district court, including issues related to Kennecott's representations to the patent examiner in prosecuting the '299 application. However, it is too late in the proceeding for Kyocera to retreat from its blanket concession of the factual issues.

The purpose of section 112, first paragraph, is to ensure that there is an adequate disclosure of the invention for which patent rights are sought. The purpose of the description requirement of this paragraph is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.

The incorporation of the requirements of section 112 into section 120 ensures that the inventor had possession of the later-claimed invention on the filing date of the earlier application. *In re Edwards*, 568 F.2d 1349, 1351, 196 USPQ 465, 467 (CCPA 1978). The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention. A description that does not meet this requirement is legally insufficient. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985).

It was undisputed that the only written description in the '299 application that was not present in the original '954 disclosure was the description and pictures of the product's microstructure. Kennecott points to authority that the added description of a property of a previously disclosed product does not deprive claims to that product of the benefit of a prior disclosure of the product. Kyocera responds that because the '954 specification is silent as to the microstructure of the product, and because one would not know whether the product had an equiaxed microstructure merely by reading the specification, the specification is inadequate in law to support claims that require an equiaxed microstructure. Kyocera also asserts that the equiaxed microstructure is not obtained without physical manipulation of the process of the '954 application, and that any concession it may have made as to production of an equiaxed product is limited to the specific conditions used in examples 1-30 of the '954 specification.

Taking the last contention first, it was admitted that the products of examples 1-30 have the equiaxed microstructure, and that one skilled in this art could readily determine the microstructure of the product. Kyocera's arguments on appeal as to the need for manipulation of conditions are contravened in the affidavit evidence referred to in Finding of Fact 11, *supra*. We conclude that it was established before the district court that the high-alpha products of the '954 application have the equiaxed microstructure.

On the issue of sufficiency of the earlier disclosure, the body of precedent teaches that the legal conclusion depends on the particular facts. In *In re Edwards* the court

considered a chemical compound that was not described in the earlier application, and stated that the earlier and later applications need not use the identical words, if the earlier application shows the subject matter that is claimed in the later application, with adequate direction as to how to obtain it. The court observed that the chemical reactions described in the earlier filing "will inherently produce, as the predominant component, the [later claimed] compound". 568 F.2d at 1352, 196 USPQ at 467. The facts in *Edwards* are strongly analogous to those herein, for Kennecott's '954 examples 1-30 all produce a ceramic that has an equiaxed structure.

The facts before us are not like those discussed in *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), referred to by the district court, but are analogous to those discussed in *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971). In *Reynolds* the question was whether words describing a function that was inherent in the claimed product could be added to the specification by amendment, or whether such description was "new matter". The court cited with approval the holding in *Technicon Instruments Corp. v. Coleman Instruments, Inc.*, 225 F.Supp. 630, 640-41, 150 USPQ 227, 236 (N.D. Ill. 1966), *aff'd*, 385 F.2d 391, 155 USPQ 369 (7th Cir. 1967), that:

By disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory, or advantage even though he says nothing concerning it.

Quoted at 433 F.2d at 389, 170 USPQ at 98. It was concluded that the express description of the inherent property, since not "new matter", could be added to the specification with effect as of the original filing date.

The Court of Customs and Patent Appeals has long recognized that an invention may be described in different ways and still be the same invention. In *In re Kirchner*, 305 F.2d 897, 904, 134 USPQ 324, 330 (CCPA 1962), the court held that compliance with section 120

does not require that the invention be described in the same way, or comply with section 112 in the same way, in both applications.

Id. In *Kirchner* the court authorized the addition to the specification of descriptive matter concerning the use of the compounds without loss of the parent application's filing date. In the '299 patent, by contrast, the additional material was added not only to the specification, but to the claims. Thus Kyo-

cera argues that it is immaterial that the product in the '299 claims is inherently the same as that produced in the '954 application, because unlike *Kirchner* the '299 claims include the new descriptive matter.

The Court of Customs and Patent Appeals did not adopt the position that is now urged by Kyocera. In *In re Nathan*, 328 F.2d 1005, 1008-09, 140 USPQ 601, 604 (CCPA 1964), the court held that the later-added limitation to the claims of the compound's alpha orientation was "an inherent characteristic" of the claimed subject matter, and reversed a new matter rejection. The *Nathan* court explained that "a subsequent clarification of or a change in an original disclosure does not necessarily make that original disclosure fatally defective." *Id.* at 1008, 140 USPQ at 603.

Kennecott argues that Kyocera is pressing the position rejected in *Kirchner*, wherein the court cautioned that it is necessary to avoid confusing "the invention itself which is the subject matter claimed . . . with one of the factors which is taken into consideration in determining whether the invention is or is not patentable from the standpoint of meeting 35 U.S.C. 103." *Id.* at 903-04, 134 USPQ at 329-30. The *Kirchner* court held that it was not required "that a parent case disclose the same utility as a later application to entitle the latter to the benefit of the filing date of the parent." *Id.* at 904, 134 USPQ at 330. In the case at bar the additional description was not of a new use, but of the existing physical structure of the product. On the basis of this precedent, the inclusion of the existing microstructure as a descriptive term in the '299 claims does not cause the '299 claims to lose their entitlement to the date of the first-filed '954 application.

The district court relied on *Langer v. Kaufman*, 465 F.2d 915, 913, 175 USPQ 172, 174 (CCPA 1972). In *Langer* the diffraction pattern specifically recited in an interference count was not expressly described in the specification. The court held, "To prove inherency, the burden is on appellants to show that the 'necessary and only reasonable construction to be given the disclosure by one skilled in the art is one which will lend clear support to . . . [this] positive limitation in the interference count.'" *Id.* (emphasis omitted) (quoting *Binstead v. Littmann*, 242 F.2d 766, 770, 113 USPQ 279, 282 (CCPA 1957)). The issue in *Langer* was entitlement to the benefit of constructive reduction to practice, which the court denied despite evidence that one of the experiments, Run E, produced the claimed diffraction pattern. The court has generally applied this standard of the "necessary and only reason-

able construction" as a basis for determining whether an application could, on the basis of an inherent property, support a limitation in an interference count. See, e.g., *Wagoner v. Barger*, 463 F.2d 1377, 1380, 175 USPQ 85, 86-87 (CCPA 1972); *Snitzer v. Etzel*, 531 F.2d 1062, 1076, 189 USPQ 415, 419 (CCPA 1976). This standard, arising in the interference context, is consistent with that of the other cases on the issue of compliance with section 112, first paragraph.

[1] In this case, the invention of the '299 claims is a ceramic product. That product is the same as the product in the '954 application, and has the same structure. It was conceded that anyone with a microscope would see the microstructure of the product of the '954 application. The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result.

We conclude that the district court erred in holding that the '299 claims were not entitled to the '954 filing date.

REVERSED

District Court, E. D. New York

Fromson v. Citiplate Inc.

No. 82 C 0986

Decided October 14, 1987

PATENTS

1. Patentability/Validity — In general (\$115.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Motions; dismissal of action; summary judgment (\$410.31)

Federal district court, in ruling on patent owner's motion for summary judgment on question of invalidity, must determine, after drawing all permissible inferences and resolving all significant doubts in favor of accused infringer asserting invalidity, whether accused infringer has clearly and convincingly shown invalidity.

Particular patents — Printing Plates

3,181,461, Fromson, summary judgment of invalidity as to claim four denied; infringed.
